App. No. 10/501,291
Office Action Dated January 2, 2009

REMARKS

Favorable reconsideration is respectfully requested in view of the following remarks Claims 1-2, 4-11 and 13-30 are pending.

Claim rejections - 35 U.S.C. § 103

Claims 1, 2, 4-11 and 13-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP1 002874 A2 (Komori et al.) in view of Eur. J. Biochem., 1996, Vol. 242, pp. 499-505 (Yoshida et al.) and further in view of Biochemistry, 1988, Vol. 27, pp. 5470-5476 (Montellano et al.) and further in view of US Patent No. 6,127,138 (Ishimaru et al.), and further in view US Patent No. 5,556,788 (Kwan et al.). Applicants respectfully traverse this rejection.

The rejection contends that one could have been motivated to modify the method as taught by Komori according to the teachings of Yoshida and add a degradation FAOD to the sample as a pretreatment so that a glycated amino acid as a contaminant present in the sample is degraded and removed from the sample by the degradation FAOD and glycated protein as the analyte remains in the sample, as required by claim 1. Applicants respectfully submit that the rejection is relying on the improper use of hindsight in the interpretation of the references.

In particular, Komori is focused on improving the measurement of the quantity of an analyte in a sample using a redox reaction by adding a tetrazolium compound prior to the redox reaction. Komori teaches that their invention can be applied to generally known methods for measuring components in erythrocytes, and in particular, those involving the decomposition of the sugar portions of the components by oxidation to form hydrogen peroxide (paragraphs [0002] –[0004]). Komori describes in detail that in such methods, FAOD is used to catalyze a particular oxidation reaction, and specifically, the reaction indicated by the formula (1) (paragraphs [0030]-[0039]):

$$R^1\text{-CO-CH}_2\text{-NH-}R^2 + H_2O + O_2 \rightarrow R^1\text{-CO-CHO} + NH_2\text{-}R^2 + H_2O_2 \quad (1).$$

Komori indicates that a protease can be used, and if used, the protease is added before catalyzing the above reaction with FAOD for the purposes of facilitating the FAOD to act on the analyte (paragraph [0030]).

It is clear from the above discussion that Komori is directed to solving problems caused by reducing substance that are present in blood by adding a tetrazolium compound

prior to a redox reaction, and merely teaches that their solution can be applied generally to known peroxidase-coupled reaction systems for quantifying glycated proteins.

Yoshida is directed to developing a new enzymic method for the determination of glycated proteins in serum. Yoshida notes that the prevalent methods for such a determination are HPLC and fructosamine method, and that the specificities of such methods are relatively low and/or the assays are somewhat tedious when examining a great number of samples (page 499, column 1, second paragraph). In order to address such problems, Yoshida describes the possible use of FAODs from different fungi that are specific to model compounds of glycated albumin and glycated hemoglobin (page 499, column 2, second full paragraph). Yoshida indicates that they expect that their FAODs can be used for the determination of both HbA1c and glycated albumin (Id.). In order to study the activities of their FAODs, a peroxidase-coupled reaction system was used (page 500, column 1, third full paragraph).

It is clear from the above discussion that Yoshida is directed to studying FAODs from different fungi and in particular to their specificity to glycated albumin and glyacted hemoglobin by studying their activities towards model compounds of the glycated proteins in known peroxidase-coupled reaction systems, the activities being the catalytic activities to form the hydrogen peroxide.

The rejection contends that one could have been motivated to modify the method as taught by Komori in view of Yoshida to provide a method for measuring an amount of glycated protein in a sample with predictable results of removing the contaminant glycated amino acid, the motivation taught by Yoshida being to provide a more sensitive enzymatic method. However, Komori merely describes known peroxidase-coupled reaction systems where FAODs are used only for the purposes of quantifying components in erythrocytes including glycated amino acids as analytes. Yoshida merely teaches the use of FAODs that might be specific to certain glycated proteins, namely glycated albumin and glycated hemoglobin. As such, the references taken together merely suggest the use of alternative FAODs in known peroxidase-coupled reaction systems for the purposes of specifically quantifying both glycated albumin and glycated hemoglobin, and are far from establishing that a degradation FAOD can be used for purposes of removing specifically a glycated amino acid as contaminants, as opposed to glycated protein as an analyte, from a sample before

initiating the peroxidase-coupled method to quantify the remaining analyte. In fact, the references clearly fail to recognize the problem of even having unwanted glycated amino acids formed from exogenous substances administered via an intravenous drip or the like that can affect the accuracy in the measurement of the glycated protein and the solution provided by claim 1. Nothing in the references teaches or suggests adding a degradation FAOD to the sample as a pretreatment so that a glycated amino acid as a contaminant present in the sample is degraded and removed from the sample by the degradation FAOD and glycated protein as the analyte remains in the sample, as required by claim 1. Accordingly, claim 1 and the dependent claims therefrom are patentable over the references.

The rejection contends that once the method of measuring an amount of glycated protein in an analyte was established, providing a measuring kit of claim 9 to determine the amount of the glycated protein would become obvious in view of Ishimaru et al. However, as discussed above, Komori and Yoshida merely describe the use of FAODs for its catalytic activity to form hydrogen peroxide in the peroxidase-coupled method. Nothing in the references teaches or suggests using a pretreatment reagent containing a first FAOD that is present in an amount suitable for the degradation of a glycated amino acid as a contaminant present in the sample as required by claim 9. Accordingly, claim 9 and the dependent claims therefrom are patentable over the references, taken alone or separately.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. Box 2902
Minneapolis, MN 55402-0902
(612) 455-3800

Dated: April 2, 2009

By: _____
Douglas P. Mueller
Reg. No. 30,300

DPM/ym